FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS ABOUT DRUG PRODUCTS (0910-0677)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION: Testing Messages to Improve Consumer Knowledge about Prescription Drug Risks and Benefits

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA is seeking OMB approval to conduct a focus group study to evaluate communication messages that aim to provide consumers with the balanced risk-benefit context they need to make prescription drug use decisions. FDA recently developed the messages based on findings from an initial series of OMB-approved focus groups conducted in 2010. FDA now seeks public input as it assesses the potential effectiveness of its messages in successfully communicating with intended audiences.

   Stories about newly discovered risks of some prescription drugs (e.g., Avandia, Vioxx, some antidepressants) and certain medical devices (e.g., coronary stents) have made headlines in major newspapers and broadcast media. FDA has been told by many concerned healthcare providers that their patients are learning about relevant product problems, and often taking inappropriate action (e.g., stopping critical medicines) even before their providers know about the issue and can institute their own communications with their patients. For FDA to plan informed programmatic communication activities, it needs better empirical data about how people might interpret the dissemination of emerging information on both the risks and benefits of medical products.

   Risk communication research demonstrates that, in the absence of benefit information, people may consider even small risks to be unacceptable. In the face of product sponsor focus on benefits, FDA has focused on product risks. However, the relative credibility of FDA versus product sponsors as information sources may make this focus problematic for consumers. Recent studies demonstrate how little consumers know about either statistics or the factors that enter into regulatory decision-making. Consequently, when consumers hear about a newly identified risk associated with a medical product they use, they will not likely process this risk within the context of either the benefits of continuing use of the product, or the risks of stopping use of the product. Thus, even though FDA believes it has objectively informed consumers, their lack of an appropriate cognitive model in which to place this information means that it is likely they have not been effectively informed.

   To effectively inform consumers about newly identified risks of medical products, FDA must understand how consumers think about both the risks and benefits of medical products. To this end, FDA conducted focus groups in 2010 as formative research to provide critical information needed about target audiences. Findings from this initial set of focus groups provided insight into the needs, decision-making processes, and misperceptions of prescription drug users and caregivers. FDA used these findings in its

planning and development of draft communications to provide consumers with the better context they need in which to place new risk information more completely.

FDA is now proposing to conduct a series of additional focus groups as initial testing of its recently developed messages. The focus group feedback will allow FDA to assess the potential effectiveness of its messages in successfully communicating with their intended audiences. The focus groups will provide real consumer reactions to help FDA assess whether the messages fill in the gaps in consumer perceptions, whether they lend credibility to the FDA as a source of risk and benefit information, and if they are useful for decision-making purposes (especially for newly emerging risks).

2. Intended use of information:

FDA expects to use the findings from this second series of focus groups to refine its messages while they are still in the developmental stage. The results of these focus groups will also help inform the FDA's newly established Risk Communication Advisory Committee and would constitute a further effort to respond to the Institute of Medicine's recommendation in its September 2006 report "The Future of Drug Safety" that FDA improve its communications with the public. The data will not be used for the purposes of making policy or regulatory decisions.

The Contractor will provide FDA with an independent analysis of the results based on the audio/video tapes and transcripts of the groups. The raw data for these reports will be the words, phrases, sentences, and non-verbal responses of the participants. The final report will be based on the discursive data gathered from each group. The report will detail the characteristics of each group and will highlight variations and commonalities between the groups. Because focus group research constitutes a qualitative methodology, quantitative results will not be reported. FDA recognizes that the data collected will not be statistically representative of population segments characterized by the groups.

3. Description of respondents:

FDA contracted with Olchak Market Research (OMR) to conduct these in-person focus groups. The Contractor will use a telephone screening facility to contact potential respondents. The screening facility will use lists of an opted-in universe of potential respondents. Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener.

Participants will be recruited from the Washington, DC metropolitan area and the San Antonio, TX area. The focus groups will be a mix of men and women and will be diverse in race/ethnicity. The groups will also be internally homogenous with respect to education and recent experience with prescription medicines to avoid interference to the dynamics of the groups that could result from vastly different experiences. At each of the two locations, the focus groups will be broken down by education: Lower Education (no college credit) and Higher Education (at least some college credit). The education groups will be further segmented by medication use in the last six months: Chronic Users (taking at least one prescription medication on at least a monthly basis), Intermittent Users (taking a prescription medication occasionally or on an "as needed" basis), and Caregivers (caring for a child less than 16 years old who is a chronic or intermittent user, as defined above). Although it is possible for participants to be eligible for multiple medication use groups, each participant will be assigned to a single group consisting of a

specific medication use segment. These internally homogenous groups are intended to limit anomalous findings from interfering with group dynamics.

4. Date(s) to be conducted and location(s):

Pending OMB approval by the date requested, focus groups are planned for the following dates and locations.

Greenbelt, MD: September 12 and 14-15, 2011
San Antonio, TX: October 18-20, 2011

5. How the Information is being collected:

Recruitment Information

The Contractor will contact potential respondents by telephone and screen them for eligibility using a participant screener. The participant screener will include items on race and ethnicity consistent with OMB standards:

Are you of Hispanic, Latino, or Spanish origin?

Yes
No

What is your race? Please select one or more.

White
Black or African American
American Indian or Alaska Native
Asian
Native Hawaiian or other Pacific Islander

Between 4-7 days before the date of a particular focus group, the Contractor will mail a confirmation letter to recruited participants. This will inform participants about how the groups will be recorded and reported, and the voluntary nature of their participation. The Contractor will also contact participants with a reminder phone call the day prior to the scheduled session. At the beginning of each group, the moderator will confirm that the participants read the consent form and orally consent to participate and to have the session taped. The consent will be taped as well.

Focus Group Discussions

A trained moderator with experience in conducting in-person focus groups will lead all discussions. The moderator will use the attached moderator guide to ensure that all relevant topic areas are addressed. The groups will focus on reactions to FDA-developed messages and how they relate to participants' personal beliefs and opinions about the risks and benefits of prescription drugs. The questions concern participants' thoughts about:

- the perceived differences between generic and name brand prescription drugs,
- the weight of risk information in deciding whether or not to fill or take prescription drugs,
- the research needed for drug reviews,
- the importance of discussing prescription drug use decisions with healthcare providers, and
- understanding FDA's role as a regulatory and public health agency.

Discussion will begin on or near the prearranged time. After short introductions, the moderator will ease the participants into a discussion of specific topics with a more general "warm-up" question. The moderator will not pose any questions of a sensitive or private nature. The moderator will continue to facilitate the discussion until all of the topics in the moderator guide have been addressed. Time is allowed to address ideas and questions spontaneously generated from the discussion. Reliability and validity will be assessed iteratively within the discussions by revisiting participants' verbalizations and asking for clarification. This will be done both within the course of the individual sessions and between the separate sessions. The groups will be audio and video taped. Written and electronic transcripts of the focus groups will be prepared from these tapes, with all personally identifying information removed. These transcripts will be used by the moderator to prepare a final report.

The Contractor will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The last names of the participants will not appear on any focus group materials. Verbatim quotes included in the final report will not be attributed to an individual.

6. Number of focus groups:

The study design (2 locations X 2 education levels X 3 medication use groups) will result in a total of 12 groups. In anticipation of demographic subgroups not being distributed equally across education levels, FDA feels the proposed study design will provide the necessary leeway to achieve a respectably diverse amount of consumer input within each group. This study design parallels the design of the initial series of OMB-approved focus groups conducted in 2010.

7. Amount and justification for any proposed incentive:

The Contractor (OMR) has recommended that participants be offered $75. These estimates are based on OMR's experience with past qualitative studies. The incentive reflects the estimated value that a focus group participant places on their free time.

OMR's long experience in this area indicates that offering an incentive that is below the accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following.

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e., Sample Size & Method of Selection):

The Contractor will recruit approximately 144 individuals, expecting to have eight to ten participants per group. No more than 12 participants will participate in a group. Past

experience has shown that this amount of over-recruitment generally ensures that enough participants will show up for the groups.

The time required for screening and participation will be two hours per participant. There will be a total of no more than 12 participants in 12 groups, producing a conservative total estimated respondent burden of 288 hours.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Prescription Drug Users and Caregivers	144	120/60	288

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